



K 960180

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**22 MM CAST CoCr HEAD AND  
POLYETHYLENE ACETABULAR SHELL LINER**

**Summary of Safety and Effectiveness Information  
Upon Which The Substantial Equivalence  
Determination is Based  
[510(k) Summary]**

The 22 mm CoCr Head and Hooded Liner are manufactured from biocompatible materials: Co-Cr-Mo alloy and ultra-high molecular-weight polyethylene (UHMWPE). These materials are in current use in numerous hip systems and their use has been established through many years of successful clinical application.

Fatigue testing of the stem and 22 mm head was satisfied under previously released 510(k) submissions. Likewise, the liner testing was satisfied under previous 510(k) submissions since only the I.D. has been changed.

A smaller CoCr head with appropriate liner was manufactured to increase polyethylene minimal thickness in the smaller diameter acetabular cups. These components will supplement 28 mm CoCr heads and liners already released in the ProForm and Provident Hip Systems. Only certain neck lengths are available in the 22 mm head in order to provide adequate support.